REMARKS

The present invention is directed to methods of treatment for specific non-*albicans* species of *Candida* isolates using antimycotic delivery systems. These systems are suitable for use in the vaginal cavity. The invention is additionally directed to methods utilizing preparations demonstrating a controlled, extended or sustained release of the active and/or therapeutic agent requiring a minimal number of administrations to achieve efficacy upon administration of said delivery system.

Claims 1-27 are pending in the present application. In view of the following remarks, further and favorable consideration is respectfully requested.

REJECTION UNDER 35 U.S.C. §102(b):

Claims 9 and 24-27 remain rejected under 35 U.S.C.§102(b) as being anticipated by Brown, et al., *Journal of Reproductive Medicine*, in view of Stedman's Medical Dictionary ("Brown" and "Stedman's", respectively).

Applicants respectfully traverse the rejection of claims 9 and 24-27 under 35 U.S.C. §102(b) and request reconsideration and withdrawal thereof.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

"For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art…The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." *See In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). Although the disclosure requirement presupposes the knowledge of one skilled in the art, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. *Id.*

"**Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**" *See In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981) (Emphasis Added). "Occasional results are not inherent." *See Mehl/Biophile International Corp. v. Milgraum,* 192 F.3d 1362 (Fed. Cir. 1999). "A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations." *See Continental Can Company USA, Inc., supra.*

Claim 9 is directed to a method for the treatment of an unidentified vulvovaginal fungal condition, which comprises: administration to said fungal condition a bioadhesive, single dose treatment formulation comprising from about 0.500 to about 5.000% w/w butoconazole nitrate; and wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis, tropicalis, glabrata, parapsilosis, krusei,* and *lusitaniae.*

Claim 24 is directed to a method for the treatment of an unidentified vulvovaginatis condition comprising: treating a condition caused by a species of *Candida* selected from the group consisting of *C. dubliniensis, C. tropicalis, C. glabrata, C. parapsilosis, C. krusei,* and *C. lusitaniae* by applying to the vaginal tissue a multiphase formulation in a single dose to provide a *Candida* species kill rate of about 50 to about 100% for a period of at least about 4 days. Claims 25-27 all depend, from claim 24.

Applicants submit that Brown in view of Stedman's does not expressly or inherently teach each and every element of the claims 9 or 24-27 as required for anticipation under 35 U.S.C. § 102(b).

As discussed in Applicant's previous response filed February 8, 2007, Brown is directed to a comparison of the safety and efficacy of (1) a single vaginal dose of butoconazole nitrate 2% sustained release cream with (2) a seven day schedule of miconazole nitrate 2% vaginal cream in the treatment of vulvovaginal candidias caused by *C. albicans*. See, Objective, Introduction, Patient Selection, and Results: Microbiological Cure Rate sections. Steadman's simply provides a definition for "cream" as meaning a semisolid emulsion of either the oil-in-water type, ordinarily intended for topical use.

Applicants reiterate, Brown in view of Stedman's does not teach administration of a bioadhesive single dose treatment formulation comprising from about 0.500 to about 5.000% w/w butoconazole nitrate to a vulvovaginal fungal condition caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* as recited in claim 9. Additionally, Brown in view of Stedman's does not teach treating a **condition caused by a species of *Candida* selected from the group consisting of *C. dubliniensis*, *C. tropicalis*, *C. glabrata*, *C. parapsilosis*, *C. krusei*, and *C. lusitaniae*** by applying to the vaginal tissue a multiphase formulation in a single dose to provide a *Candida* species kill rate of about 50 to about 100% for a period of at least about 4 days as recited in claim 24.

However, at page three of the Official Action, the following is set forth:

> Brown et al. clearly discloses on page 934, lower right column that butoconazole nitrate has a "broad antifungal spectrum consistently showing high activity against the most important eight non-*albicans* Candida species" and

> "inhibiting the growth of C. *albicans* as well as the non-*albicans* pathogens species." Furthermore, Brown et al. treated 101 patients with butaconazole nitrate and stated that 10-20% of the cases are non-*albicans* Candida species and *C. glabrata* is the second most frequently encountered species (Page 934, left column and page 936, Table 1). Thus Brown et al. disclose treatment of vulvovaginal fungal caused by at least *C. glabrata*. Simply because Brown et al. did not test for the presence of other species of Candida, does not mean that there were not present especially in light of the [asserted] fact that 10-20% for the cases are caused by non-*albicans* Candida species. The treatment of other Candida species in the method of Brown et al. is inherent in the method. *See* Official Action at page 3.

Applicants respectfully disagree. It is asserted that of the 101 patients tested in Brown et al., at least 10-20% of the cases were infected with non-*albicans* Candida species. It is further asserted that "Brown et al. disclose treatment of vulvovaginal fungal caused by at least *C. glabrata*." *See* Supra. This line of reasoning is used to draw a nexus between the study preformed in Brown et al. with background information provided by the authors of Brown et al. This line of reasoning is incorrect. If one refers to the passage in Brown et al. regarding patient selection, one finds the following:

> Healthy, nonpregnant women with clinical signs and symptoms of vulvovaginal candidiasis participated in the study. KOH vaginal smers and samples of vaginal fluid were cultured on Sabouraud's and Micosel media (BBL Microbiology Systems, Cockeysville, Maryland) and confirmed or excluded the clinical impression of vulvovaginal candidiasis. **Two microbiologic laboratories identified blindly the presence of C *albicans*.** Examination of wet smears showing trichomonads or clue cells associated with bacterial agents excluded patients from enrollment. A test for gonadotropin was performed prior to admission to the study. (Emphasis Added). *See* Brown et al. at page 935, column 2, paragraph 3.

Hence, the 101 patients studied in Brown et al. were strictly chosen on the basis of exhibiting the presence of C. *albicans*, and

not just for exhibiting symptoms of vulvovaginal candidiasis alone. In fact, it would appear those women with **symptoms** of vulvovaginal candidiasis alone, who did not test positive for C. *albicans*, would have been excluded on that fact alone. Nowhere in Brown et al. is it either expressly or inherently taught that any of the 101 patients tested positive for a **condition caused by a species of *Candida* selected from the group consisting of *C. dubliniensis*, *C. tropicalis*, *C. glabrata*, *C. parapsilosis*, *C. krusei*, and *C. lusitaniae* or that the same could be treated.**

According to the holding of *In re Oelrich,* "**Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**" *See supra, In re Oelrich.* Although Brown et al. teaches that vulvovaginal Candidiasis is **caused by *C. albicans*** as well as non-albicans pathogenic species, Brown only teaches that the single-dose butoconazole is **effective in treating *C. albicans*, alone**. *See* Brown at page 934 and page 936, second paragraph.

Futher, Brown et al. teaches that C. *glabrata* "is less susceptible to standard treatment." *See* Brown et al. at page 934, lower left column. Hence, Brown et al. does not teach any effective treatment of C. glabrata. Brown et al. only describes, firsthand, the treatment of C. *albicans*.

With regard to second hand knowledge described in Brown et al., at page 934, lower right column, "that butoconazole nitrate has a broad antifungal spectrum consistently showing high activity against the most important eight non-*albicans* Candida species" and "inhibiting the growth of C. *albicans* as well as the non-*albicans* pathogens species." However, Applicants note, as footnoted by

Brown et al., the basis for this passage comes from a previously published article, Lynch, ME, Sobel, JD: *Comparative in vitro activity of antimcotic agents against pathogenic vaginal yeast isolates*, J Med Vet Mycol (1994), 32:267-274, provided herewith for the Examiner's convenience.

Applicants respectfully submit that the treatments defined by the presently pending claims based on *in vivo* studies are distinguishable from the *in vitro* susceptibility noted by Lynch and Sobel. Further, as admitted by Lynch and Sobel, the results of their tests show that more testing in the area must be performed on non-*albicans* Candida. As evidence of the foregoing, the last paragraph at page 273 of Lynch and Sobel, states:

> **It is important to emphasize that *in vitro* susceptibility cannot always be extrapolated into predicting *in vivo* activity or clinical success even when an agent is applied locally resulting in high concentrations of the antifungal agent.** There have been relatively few published studies comparing *in vitro* activity of azoles against non-C. *albicans* species and clinical outcome in animal models or in patients. It is our experience however, that clinical cases of C. *glabrata* and S. *cervisiae* vaginitis respond less well to the majority of available therapies. **Since a successful animal model of C. *glabrata* vaginitis has not been established**, most of our information is based upon limited experience with clinical C. *albicans* vaginitis. Nevertheless, in two studies, in two studies, *in vitro* sensitivity tests performed on C. glabrata and S. *cerevisiae* were useful in predicting clinical failure with TER and FLU and moderate success with CLO [9, 13]. **The role of cidal activity of antifungal agents in determining the outcome of fungal vaginitis, especially when caused by species other than C. *albicans*, is unknown.** This may be a critical factor in determining, not the immediate outcome of therapy in alleviating symptoms, but the relapse and later reccurence rate, particularly of C. *glabrata* vaginitis. **This study identifies the need for futher investigation on the role of BUTO and ITRA in experimental and clinical vaginitis,especially when caused by non-*albicans Candida* species.** (Emphasis Added). *See* Lynch and Sobel at page

273.

Therefore, Applicants submit, Brown et al. **do not disclose** an effective treatment for a vulvovaginitis condition **caused by** a non-*albicans* Candida selected from the group consisting C. dubliniensis, C. tropicalis, C. glabrata, C. parapsilosis, C. krusei, and C. lusitaniae with a single dose **treatment** of butoconazole. As established above, "**Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**" Therefore, Applicants submit Brown et al. does not expressly or inherently anticipate the presently pending claims.

Accordingly, Applicants submit Brown et al. in view of Steadman's does not teach each and every element of claims 9 and 24-27, as required for anticipation under 35 USC § 102(b). Therefore, Applicants respectfully request the Examiner reconsider and withdraw this rejection.

REJECTION UNDER 35 U.S.C. §103(a):

Claims 1-27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Riley in U.S. Patent No. 5,266,329 (the '329 patent), in view of Brown, *supra,* and Garg in *Pharmaceutical Tech. Drug Delivery* ("Garg"), Droegemueller et al. in *Obstet. Gynecol* ("Droegemueller") and Chen in U.S. Patent No. 2,267,985 (the 985 patent).

Applicants respectfully traverse the rejection of claims 1-27 under 35 U.S.C. §103(a). A *prima facie* case of obviousness has not been established with respect to the '329 patent, in view of Brown

and Garg and Droegemueller for the reasons set forth below.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Further, according to MPEP § 2141, "Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383

U.S. 1, 148 USPQ 459 (1966), stated:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquires may have relevancy…." *See* MPEP § 2141(1).

Accordingly, the four factual inquiries determining nonobviousness are:

> (A) Determining the scope and contents of the prior art;
>
> (B) Ascertaining the differences between the prior art and the claims in issue;
>
> (C) Resolving the level of ordinary skill in the pertinent art; and
>
> (D) Evaluating evidence of secondary considerations. *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966); Followed by *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

It is submitted that a *prima facie* case of obviousness has not been established according to the factors enumerated by Supreme Court in *Graham v. John Deere*.

Applicants respectfully submit that the scope and contents of the prior art has been incorrectly determined. According to MPEP § 2141.01(III), content of the prior art is determined at the time the invention was made to avoid hindsight. The requirement "at the time the invention was made" is to avoid impermissible hindsight. "It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made, to occupy

the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Applicants respectfully submit the teachings of Brown et al. as evidenced by the additional publications of J.D. Sobel, demonstrate that Brown et al., were unaware of a viable method for effectively treating the claimed non-*albicans* Candida species. Examples of Sobel's publications include: Sobel, JD, "Treatment of vaginal Candida infections," *Expert Opin Pharmocother*, 3(8): 1059-65, Aug 2002; Moosa, MY and Sobel JD, "Non-*albicans* Candida infections in patients with hematologic malignancies," *Semin Respir Infect.*, 17, (2): 91-8, Jun 2002; Sobel et al., "Treatment of Complicated Candida vaginitis: comparison of single and sequential doses of fluconazole," *Am J Obstet Gynecol.*, 185(2): 363-9, Aug 2001; Sobel JD, "Antimicrobial Resistance in Vulvovaginitis," *Curr Infect Dis Rep*, 3(6): 546-549, Dec 2001, abstracts of each are attached hereto for convenience. The attached Sobel publications, published subsequent to Brown et al., relate to treatment of the different Candida species using various active agents in order to determine efficacy. Such research efforts clearly show that much remained unknown at the time Brown et al. was written. Therefore, the assertion that Brown et al. disclose each and every limitation of the subject pending claims is only possible when viewed with impermissible hindsight.

The state of the art at the time the subject application was filed would not consider the use of a bioadherant, single dose treatment for a vulvovaginitis condition caused by non-albicans species of *Candida*; specifically, *C. dubliniensis*, *C. tropicalis*,

C. glabrata, *C. parapsilosis*, *C. krusei*, and *C. lusitaniae*. According to Lynch and Sobel, "[t]here have been relatively few published studies comparing *in vitro* activity of azoles against non-C. *albicans* species and clinical outcome in animal models or in patients." *See Lynch and Sobel at page 273*. Concluding the article, Lynch and Sobel state, "[t]his study identifies the need for further investigation on the role of BUTO and ITRA in experimental and clinical vaginitis, especially when caused by non-*albicans* Candida species."

As evidence additional evidence that the state of the art at the time the subject application was filed would not consider the use of a bioadherant, single dose treatment for a vulvovaginitis condition caused by non-albicans species selected from the group consisting of *C. dubliniensis*, *C. tropicalis*, *C. glabrata*, *C. parapsilosis*, *C. krusei*, and *C. lusitaniae*, Applicants submit herewith a copy of a study published by Nyirjesy et al. on non-*albicans* Candida, and its role in vaginitis **subsequent to the filing date of the present application**. *See* Nyirjesy et al., "Vaginal *Candida parapsilosis:* Pathogen or bystander?" *Infectious Diseases in Obstertrics and Gynecology*, 13(1):47-41, March 2005. According to the Nyirjesy et al. study, "*Candida parapsilosis* has been identified as a vaginal isolate, but little evidence exists to support its role as a vaginal pathogen." *See* Nyirjesy et al. at p. 37, sentence bridging the first and second columns. Further, regarding *C. parapsilosis*, Nyirjesy et al. note "there have been no studies that look specifically at its relevance to symptoms." *See Id.* at p. 38, top of the first column. Finally, according to Nyirjesy et al., "**some investigators have questioned whether some non-*C. albicans* species cause vulvovaginal symptoms at all.**" *See Id.* at p. 39, in the first full paragraph in the second column. In view of Nyirjesy et al., it is clear that the state of the art at

the time the present application was filed would not have considered the presently claimed subject matter.

Applicants submit that the scope and content of the prior art has been misconstrued. As evidenced by the express text of Lynch and Sobel, a need for further investigation on the role of Butoconazole (and Itraconazole) in experimental vaginitis was needed, especially with regard to vaginitis caused by non-*albicans* species. Additionally, as evidenced by the abstracts submitted herewith, Applicants note Sobel, even after Brown et al. was published, did not appear to obtain the presently claimed subject matter. Accordingly, Applicants submit that a person of ordinary skill in the art could only arrive at the presently pending subject matter by way of in permissible hindsight, i.e., construing the scope and contents of the prior art in view of the teachings of the present application.

b. All Elements Not Taught or Suggested

All of independent claims 1-35 are, generally, directed to the use of a bioadherant, single dose **treatment** of a vulvovaginitis condition **caused by** non-albicans species of *Candida*. Specifically, claims 1-35 are directed to treating conditions caused by *Candida* species including: *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

The '329 patent teaches systems, methods of preparation and administration of the release of an active agent in a controlled manner for an extended period in a vaginal cavity environment. The disclosure teaches that when the systems incorporate an antifungal agent, i.e., an imidazole, the conventional treatment time may be reduced by at least 25%. Specifically, the '329 patent teaches

that the conventional treatment period or quantity of agent used is reduced by at least 25%, whereas normally a controlled release drug system reduces the number of times a day that a drug must be administered rather than the overall length of treatment. See, col. 4, lines 5-20. The '329 patent teaches that tests utilizing imidazoles upon *C. albicans* have demonstrated this result.

As discussed above, the presently claimed subject matter is the use of a **bioadherant, single dose** treatment of a vulvovaginitis condition caused by **non-*albicans*** species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*. The '329 patent does not teach or suggest the use of a bioadherent, single-dose treatment of a vulvovaginatis condition caused by non-albicans as presently claimed. Therefore, the '329 patent does not teach each and every element of the presently pending claims as required by *In re Wilson*.

Brown et al. is discussed above with regard to the rejection under 35 U.S.C. § 102(b). Brown et al. is directed to a comparison of the safety and efficacy of (1) a single vaginal dose of butoconazole nitrate 2% sustained release cream with (2) a seven day schedule of miconazole nitrate 2% vaginal cream in the treatment of vulvovaginal candidias caused by *C. albicans*.

Applicants reiterate, the presently claimed subject matter is the use of a **bioadherant, single dose** treatment of a vulvovaginitis condition caused by **non-*albicans*** species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

Brown et al. does not remedy the deficiencies of the '329 patent. As discussed, Brown et al. does not teach or suggest the use of a bioadherent, single-dose treatment of a vulvovaginatis condition caused by non-*albicans* as presently claimed. Therefore, whether taken alone, or in combination, the '329 patent and Brown et al. do not render the presently claimed subject matter obvious.

Garg is merely directed to pharmaceutical excipients useful in vaginal formulations. Garg simply discloses pharmaceutical excipients that may be used in a vaginal formulation. Additionally Garg et al. teach which Regulatory Status some of the excipients disclosed therein are assigned.

As discussed, the presently claimed subject matter is the use of a **bioadherant, single dose** treatment of a vulvovaginitis condition caused by **non-*albicans*** species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

Garg does not remedy the deficiencies of the '329 patent and Brown. Garg does not teach or suggest the use of a bioadherent, single-dose treatment of a vulvovaginatis condition caused by non-*albicans* as presently claimed. Therefore, whether taken alone, or in combination, the '329 patent, Brown et al. and Garg do not render the presently claimed subject matter obvious.

Droegemueller is directed to a three day treatment with butoconazole nitrate for vulvovaginal candidiasis. The teachings of Droegemuller are limited to *C. albicans*.

Again, the presently claimed subject matter is the use of a **bioadherant**, **single dose** treatment of a vulvovaginitis condition caused by **non-*albicans*** species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

Droegemueller does not remedy the deficiencies of the '329 patent, Brown and Garg. Droegemueller does not teach or suggest the use of a bioadherent, single-dose treatment of a vulvovaginatis condition caused by non-*albicans* as presently claimed. Therefore, whether taken alone, or in combination, the '329 patent, Brown et al., Garg and Droegemuller do not render the presently claimed subject matter obvious.

The '985 patent merely suggests a composition comprising an antifungal agent with polyglyceryl 2-4 oleate.

As stated, the presently claimed subject matter is the use of a **bioadherant**, **single dose** treatment of a vulvovaginitis condition caused by **non-*albicans*** species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

The '985 patent does not remedy the deficiencies of the '329 patent, Brown, Garg and Droegmueller. The '985 patent does not teach or suggest the use of a bioadherent, single-dose treatment of a vulvovaginatis condition caused by non-*albicans* as presently claimed. Therefore, whether taken alone, or in combination, the '329 patent, Brown, Garg, Droegemueller and the '985 patent do not render the presently claimed subject matter obvious a *prima facie case* of obviousness under 35 U.S.C. § 103(a) has not been established.

For these reasons, in addition to others not noted herein, Applicants submit a *prima facie* case obviousness has not been established. Accordingly, withdrawal of the subject rejection and allowance of claims 1-35 is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit the pending claims are in condition for allowance. Early notice to this effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

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